REMARKS/ARGUMENTS

Claims 7, 9, 13, 15, 19, and 32-33, 35-36, and 38-44 are pending in this application and presented for examination. Independent claims 7, 13 and 19 have been amended. No new matter has been added with the foregoing amendments. Reconsideration is respectfully requested.

I. CLAIM OBJECTIONS

The Examiner alleges that claims 7 and 13 read on both a product and a method. In order to expedite allowance of the subject application, Applicants have made it clear that the present invention is a nasal composition for mucosal nasal administration. The nasal composition is administered nasally. The claim language is analogous to an oral composition which is administered orally, or for oral administration. Such claim language is customary.

In view of the amendments and remarks, Applicants respectfully request the Examiner withdraw the objection.

II. FIRST REJECTION UNDER 35 U.S.C. § 102(b)

Claims 7, 9, 13, 15, 19, 31-33, 35-36 and 38-39 were rejected as allegedly being anticipated under 35 U.S.C. § 102(b) by Takasu. To the extent the rejection is applicable to the amended set of claims, Applicants respectfully traverse the rejection. Applicants respectfully note that claim 31 is not pending.

Under MPEP § 2131:

> [a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

As amended, claim 7 recites:

> (Currently amended) A nasal composition for nasal mucosal administration, said nasal composition comprising a mucosal adjuvant for inducing both vaccine antigen-specific antibody in blood and vaccine antigen-specific antibody secreted at the mucosal surface, wherein said nasal composition comprises a natural interferon α as the active ingredient of said mucosal adjuvant and wherein nasal mucosal administration of said mucosal adjuvant is performed at the same time as administration of a vaccine antigen, wherein said vaccine antigen comprises a protein or peptide antigen, and wherein the vaccine antigen-specific antibody is secreted at the gastrointestinal mucosal surface.

Takasu does not teach or suggest a composition having a natural interferon α and a vaccine antigen **together** as a composition as is currently claimed. In Takasu, the flu peptide is administered by osmotic pump and the INFα is administered by injection, separately. In addition, Takasu does not teach or suggest a nasal composition, wherein the nasal composition is administered through the nose.

In fact, Takasu teaches away from the present invention. For example, on page 174, left hand column, 12 lines from the bottom, Takasu teaches an osmotic pump administration of a flu peptide with INFα being injected, compared with a flu peptide and INFα being injected. The latter type of administration did not work.

In addition, these results show that *In re Papesch* 315 F.2d 381, 391, 137 USPQ 43, 51 (CCPA 1963) is inapplicable here ("From the standpoint of patent law, a compound and all its properties are inseparable."). First of all, it is not a compound as in *In re Papesch*, (2,4,6 - Trialkylpyrazolo [4,3-d]-4,5,6,7-Tetrahydropyrimidine-5,7–Diones), but a nasal composition of INFα and an antigen. As Takasu teaches, the way the two components are administered can elicit different results and efficacies. Here it is clear, Takasu does not teach a nasal administration of the two components at the same time as is currently claimed. As such, there is simply no anticipation. As each and every element of the claim must be in the cited reference, Applicants respectfully request that the Examiner withdraw the rejection.

III. SECOND REJECTION UNDER 35 U.S.C. § 102(b)

Claims 7, 9, 13, 15, 19 and 31-33, 35-36 and 38-39 are rejected as allegedly being anticipated under 35 U.S.C. § 102(b) by Tovey. To the extent the rejection is applicable to the amended set of claims, Applicants respectfully traverse the rejection.

Under MPEP § 2131:

> [a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Tovey teaches a method for stimulating the immune response by administering an interferon via oromucosal contact. There is no teaching or suggestion of a mucosal adjuvant comprising a natural interferon α *and* an antigen comprising a protein or peptide antigen being administered via the nasal mucosal eliciting a systemic immune response as well as a mucosal immune response. In other words, Tovey *does not teach* the antigen being present in the composition.

It is respectfully noted that the Examiner admits that Tovey does not teach the inventive composition. (Page 11, point 3, last paragraph.) As each and every element of the claim must be in the cited reference, Applicants respectfully request that the Examiner withdraw the rejection.

IV. THIRD REJECTION UNDER 35 U.S.C. § 102(b)

Claims 7, 9, 13, 15, 31-33, and 35-36 are rejected as allegedly being anticipated under 35 U.S.C. § 102(b) by Foster *et al.* To the extent the rejection is applicable to the amended set of claims, Applicants respectfully traverse the rejection. Applicants respectfully note that claim 31 is not pending.

Under MPEP § 2131:

> [a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

As amended, the claims recite a nasal composition for nasal mucosal administration. Foster *et al.* do not teach or suggest a nasal composition as is claimed, wherein the nasal composition is administered through the nose.

Foster *et al.* teach "[w]e have now found that B cell proliferation can be induced by certain IFN-α subtypes." Column 1, lines 52-53. Clearly, the specification and claims of Foster *et al.* only teach the use of a IFN-α subtype not IFN-α as claimed. There is no teaching that an IFN-α subtype will elicit both vaccine antigen-specific antibody in blood *and* vaccine antigen-specific antibody secreted at the mucosal surface as is currently claimed.

As each and every element of the claim must be in the cited reference, Applicants respectfully request that the Examiner withdraw the rejection.

V. FIRST REJECTION UNDER 35 U.S.C. § 103(a)

The Examiner has maintained the rejection of claims 7, 9, 13, 15, 19, 31-33, 35-36 and 38-41 under 35 U.S.C. § 103(a) as allegedly being obvious in view of the combination of WO 00/20028 ("Staats *et al.*") and *Kurume Med J., 2001,* Vol. 48, p. 171-174 ("Takasu"). To the extent the rejection is applicable to the amended set of claims, Applicants respectfully traverse the rejection. Applicants respectfully note that claim 31 is not pending.

Staats *et al.* do not teach or suggest the use of IFN-α as claimed. Takasu simply does not teach nasal administration nor that the antibodies are secreted at the gastrointestinal mucosa as is currently claimed. Moreover, there is simply no indication that the method of Takasu invokes the humoral immune response by secreting antibodies as claimed and involving

Th2 activation and cytokine production. The CTL induction as taught by Takasu is restricted to cell-mediated immunity which involves T-lymphocytes.

Takasu teaches that the antigen peptide is administered continuously by *osmotic pump*, while the INF-α is *injected* at the site of peptide inoculation. There is absolutely no teaching or suggestion of a nasal administration as is currently claimed, nor is there any teaching of the adjuvant and the peptide being administered as a composition at the same time.

In fact, Takasu teaches away from the present invention. For example, on page 174, left hand column, 12 lines from the bottom, Takasu teaches an osmotic pump administration of a flu peptide with INFα being injected, compared with a flu peptide and INFα being injected. The latter type of administration did not work. In view of Taksu, the only way to administer would be to use osmotic pump administration of a flu peptide with INFα being injected.

Accordingly, Applicants request that the Examiner withdraw the rejection.

VI. SECOND REJECTION UNDER 35 U.S.C. § 103(a)

Claims 7, 9, 13, 15, 19, 31-33, 35-36 and 38-41 remain rejected under 35 U.S.C. § 103(a) as allegedly being obvious over U.S. Patent No. 6,436,391 ("Foster *et al.*") in view of U.S. Patent No. 6,361,769 ("Tovey"). To the extent the rejection is applicable to the amended set of claims, Applicants respectfully traverse the rejection. Applicants respectfully note that claim 31 is not pending.

Foster *et al.* teaches the following:

> We have now found that B cell proliferation can be induced by certain IFN-α subtypes. Thus, it is possible to stimulate a subject's immune response and in particular the subtypes can be used as adjuvants to increase the effectiveness of vaccines.
>
> Thus, in a first aspect the present invention provides an adjuvant for a vaccine comprising an IFN-α subtype. In particular the invention provides an adjuvant for a vaccine which comprises IFN-α8 and/or IFN-α14.
>
> The adjuvant of the present invention can be co-administered with a vaccine or could itself form part of the vaccine itself.

> Thus, in a second aspect the present invention provides a vaccine comprising at least one IFN-α subtype, preferably IFN-α8 and/or IFN-α14. (See, column 1, lines 52-56.)

However, Foster *et al.* clearly state that not all subtypes work. Foster *et al.* states as follows:

> The results show that all the IFN-α subtypes caused an increase in B cell proliferation, with the exception of IFN-α-1, which is inactive at the concentrations used in the experiment. (column 2, lines 31-34).

Given that some subtypes were effective and another subtype was totally ineffective, a skilled person would have no expectation of success using IFN-α without separating the molecule into various subtypes.

Tovey teaches a method for stimulating the immune response by administering an interferon via oromucosal contact. There is no teaching or suggestion of a mucosal adjuvant comprising a natural interferon α *and* an antigen comprising a protein or peptide antigen being administered via the nasal mucosal eliciting a systemic immune response as well as a mucosal immune response. In other words, Tovey does not teach the antigen being present in the composition. Accordingly, Applicants request that the Examiner withdraw the rejection.

VII. THIRD REJECTION UNDER 35 U.S.C. § 103(a)

Claim 41 was rejected as allegedly obvious under 35 U.S.C. § 103(a) over either Takasu or Foster *et al.* To the extent the rejection is applicable to the amended set of claims, Applicants respectfully traverse the rejection.

Claim 41 depends upon claim 19. Claim 19 is unobvious as set forth above. As claim 19 is not obvious then claim 41 cannot be obvious because it depends from a nonobvious claim. *In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992) ("[D]ependent claims are nonobvious if the independent claims from which they depend are nonobvious."). Accordingly, Applicants respectfully request that the Examiner withdraw the rejection.

VIII. FOURTH REJECTION UNDER 35 U.S.C. § 103(a)

Claims 42-44 are rejected as allegedly being obvious under 35 U.S.C. § 103(a) over Takasu in view of Kawashima *et al.* In response, Applicants respectfully traverse the rejection.

Takasu has been discussed. Kawashima *et al.* has nothing at all to do with nasal administration of a vaccine as claimed. In the abstract, Kawashima *et al.* teach oral administration. There is absolutely no teaching or suggestion of using the composition as claimed. Further, "dependent claims are nonobvious if the independent claims from which they depend are nonobvious." (*In re Fritch,* 972 F.2d 1260, 1266 (Fed. Cir. 1992)). Accordingly, Applicants respectfully request that the Examiner withdraw the rejection.

IX. FIFTH REJECTION UNDER 35 U.S.C. § 103(a)

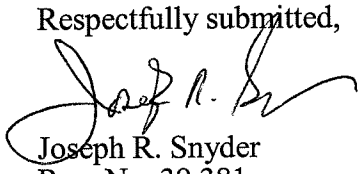
Claims 42-44 are further rejected as allegedly being obvious over Tovey in view of Kawashima *et al.* The Examiner states that Tovey is silent with regard to encapsulation, but Kawashima *et al.* supplies this teaching. In response, Applicants respectfully traverse the rejection.

Tovey has been discussed. Kawashima *et al.* has nothing at all to do with nasal administration of a vaccine composition as claimed. In the abstract, Kawashima *et al.* teach oral administration. There is absolutely no teaching or suggestion of using the composition as claimed. Further, "dependent claims are nonobvious if the independent claims from which they depend are nonobvious." (*In re Fritch,* 972 F.2d 1260, 1266 (Fed. Cir. 1992)). Accordingly, Applicants respectfully request that the Examiner withdraw the rejection.

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 925-472-5000.

Respectfully submitted,



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